

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BELLION SPIRITS, LLC, *et al.*,

Plaintiffs,

v.

UNITED STATES OF AMERICA, *et al.*,

Defendants.

Civil Action No. 17-2538 (JEB)

MEMORANDUM OPINION

A vodka maker’s hopes of advertising the health benefits of its product were thwarted when a federal administrative agency found the claims to be unsubstantiated. This vodka maker, which is actually two entities — Plaintiffs Bellion Spirits, LLC and Chigurupati Technologies Private Ltd. (jointly, “Bellion”) — then filed suit in this Court against the administrative agency — the Alcohol and Tobacco Tax and Trade Bureau (TTB) — and a host of other governmental entities. Bellion asserts claims under the Administrative Procedure Act and the First and Fifth Amendments to the U.S. Constitution. In this litigation’s first volley, Plaintiffs seek to supplement the record with two peer-reviewed scientific articles and three declarations. Finding that this case does not present one of the narrow circumstances in which a party can supplement an administrative record on judicial review, the Court will deny the Motion.

I. Background

Given the early stage of this litigation, a cursory rehearsal of the facts will do. Bellion Spirits is an independent distributor of Bellion Vodka, which is infused with NTX, a proprietary blend of ingredients developed by Chigurupati Technologies. See ECF No. 16 (Am. Compl.), ¶¶ 15–16. Plaintiffs sought approval to add eight claims espousing the health benefits of NTX to

the label of Bellion Vodka. These statements included, among other things, that NTX reduces “alcohol-induced oxidative damage to the liver,” “helps maintain normal liver enzyme production and function,” “helps protect DNA from alcohol-induced damage,” and “reduces alcohol-induced DNA damage.” *Id.*, ¶ 24. Under the applicable regulatory regime, Bellion first had to pass through TTB’s administrative process before printing these claims, as the agency’s governing regulations prohibit health-related claims that are false or misleading. *See* 27 C.F.R. § 5.42(b)(8)(ii)(A). A sub-category of such statements — those that make a “specific health claim” — must also be “adequately substantiated by scientific or medical evidence,” among other additional requirements. *Id.* § 5.42(b)(8)(ii)(B)(2); *see also id.* §§ 4.39(a)(1), 7.29(a)(1).

Bellion thus filed a petition with TTB, which sought the Food and Drug Administration’s counsel in evaluating the health claims. *See* ECF No. 22 (Pl. Motion) at 4; ECF No. 23 (Def. Opp.) at 4. After receiving and reviewing a memorandum from the FDA memorializing its findings, TTB denied Bellion’s petition. It found that “none of the eight claims is adequately substantiated” and their inclusion on a label would “create a misleading impression as to the effects on health consumption of alcoholic beverages infused with NTX.” Pl. Motion, Exh. F (Petition Response Letter) at 35.

Bellion, dissatisfied with TTB’s ruling, filed this suit against the agency and a number of other governmental entities, which the Court will collectively refer to as “TTB.” Plaintiffs challenge TTB’s denial of Bellion’s two claims concerning NTX’s effect on DNA, but raise no opposition to TTB’s denial of the other six here. *See* Am. Compl., ¶¶ 1, 24. Plaintiffs bring both statutory and constitutional causes of action. In their statutory count, Bellion contends that, by relying on the FDA’s advice, TTB acted beyond its authority and thus ran afoul of the APA

(Count III). See 5 U.S.C. § 706(2)(C); Am. Compl., ¶¶ 89–101. Only TTB, and not the FDA, Plaintiffs posit, may regulate the sale of alcohol. See Am. Compl., ¶¶ 93–94.

Bellion also advances three constitutional claims, two of which arise under the First Amendment. In one (Count I), Plaintiffs take issue with TTB’s conclusion that Bellion’s health claims are not substantiated by credible scientific evidence. They allege various errors in TTB’s conclusion and assert that, because Bellion’s claims are in fact supported by credible evidence, barring them violates Plaintiffs’ First Amendment rights. Id., ¶¶ 71–79. Bellion’s second First Amendment claim (Count II) takes a categorical shot at TTB’s procedures. Plaintiffs contend that the applicable regulations amount to an unconstitutional prior restraint because they lack definite standards for approving a label’s health-related claims and do not impose on the agency any timeframe for responding to a petitioner’s request, thus granting the agency “unbridled discretion.” Id., ¶ 86. In a similar vein, Bellion’s last constitutional cause of action asserts that TTB regulations are unconstitutionally vague. They thus bring a “facial and as-applied challenge” under the Fifth Amendment’s Due Process Clause (Count IV). Id., ¶ 103.

Before any briefing on the merits of the parties’ dispute has occurred, Bellion now moves to supplement the administrative record with five documents and the testimony of two live witnesses. The first two documents are peer-reviewed studies that, Plaintiffs say, support their claims about NTX’s effect on alcohol-induced DNA damage. See Pl. Motion at 10–11. TTB, however, did consider these studies before their publication in peer-reviewed literature, and those earlier versions are indeed part of the administrative record. Plaintiffs thus seek only to add to the record the fact of peer review. Id.

Bellion also wishes to submit three declarations and in-court testimony of two of those declarants. The first declaration, from Dr. Jeffrey Blumberg, concludes that credible scientific

studies support Bellion’s health claim and criticizes FDA’s memorandum finding the contrary. Id. at 12–13. Plaintiffs also ask that Dr. Blumberg be permitted to testify at a hearing. In the second declaration, Plaintiffs attack what they see as a weakness in the logical chain that permitted TTB to deny their request. They say that TTB’s decision hinges on a conclusion that consumers would draw a particular inference from Bellion’s claims regarding the effect of NTX on DNA — namely, that “consuming an alcohol[ic] beverage infused with NTX will provide a reduction of risk from alcohol induced damage to the liver and brain.” Id. at 15 (quoting Petition Response Letter at 41). Plaintiffs thus submit the declaration of Dr. David Stewart, a marketing expert, to “explain[] what an implied claim is, and how TTB erred by finding the existence of an implied claim without requisite data to support that conclusion.” Id. at 15. They also request that Dr. Stewart have an opportunity to testify. Finally, Plaintiffs move to add an affidavit from Harsha Chigurupati, Bellion’s President and owner, “confirming that the active compound studied in the Bellion research was the commercially available Bellion Vodka.” Id. at 2. Plaintiffs say that TTB doubted this link. Id.

II. Legal Standard

In reviewing agency action, “it is black-letter administrative law that . . . a reviewing court ‘should have before it neither more nor less information than did the agency when it made its decision.’” Hill Dermaceuticals, Inc. v. Food & Drug Admin., 709 F.3d 44, 47 (D.C. Cir. 2013) (quoting Walter O. Boswell Mem’l Hosp. v. Heckler, 749 F.2d 788, 792 (D.C. Cir. 1984)). It is only in “certain limited, and highly exceptional, circumstances” that a court may permit a party to supplement the administrative record. The Cape Hatteras Access Preservation Alliance v. U.S. Dep’t of Interior, 667 F. Supp. 2d 111, 114–15 (D.D.C. 2009). There are, nonetheless, several “accepted exceptions” to the general rule barring extra-record evidence. IMS, P.C. v.

Alvarez, 129 F.3d 618, 624 (D.C. Cir. 1997). Although courts have articulated these exceptions in slightly divergent manners, see United Student Aid Funds, Inc. v. DeVos, 237 F. Supp. 3d 1, 3 (D.D.C. 2017) (noting these variations), the parties here repeat the same four exceptions. See Pl. Motion at 8; Def. Opp. at 9.

A plaintiff can supplement an administrative record by adding evidence not before the agency: “(1) when the agency failed to examine all relevant factors; (2) when the agency failed to explain adequately its grounds for decision; (3) when the agency acted in bad faith; or (4) when the agency engaged in improper behavior.” Styrene Info. & Research Ctr., Inc. v. Sebelius, 851 F. Supp. 2d 57, 63 (D.D.C. 2012) (citing IMS, 129 F.3d at 624). These four exceptions serve the same underlying purpose: they grant plaintiffs a means of securing “effective judicial review” when the agency’s failure to explain its action or improper behavior precluded the creation an adequate record. IMS, 129 F.3d at 624 (quoting Camp v. Pitts, 411 U.S. 138, 142–43 (1973)); see also Styrene Info. & Research Ctr., 851 F. Supp. 2d at 63 (“Underlying all of these exceptions is the assessment that resort to extra-record information [is necessary] to enable judicial review to become effective.”) (quoting Calloway v. Harvey, 590 F. Supp. 2d 29, 38 (D.D.C. 2008)).

III. Analysis

Because Plaintiffs’ claims arising under the APA and the Constitution implicate distinct considerations, the Court will address each separately.

A. APA Claim

Little need be said here. In their Reply brief, Plaintiffs concede that “[n]one of Bellion’s proposed extra-record evidence is relevant to Bellion’s lone APA claim” and urge the Court to

“resolve the APA claim by reviewing the extant record without regard to the scientific affidavits and testimony.” ECF No. 25 (Pl. Reply) at 5. This settles the matter.

Even had Plaintiffs not made this concession, the Court would reach the same conclusion. For the reasons articulated in its discussion of Bellion’s constitutional claims, none of the accepted exceptions to the general rule barring extra-record evidence applies. Nor is there any other reason that such material should be considered here. The core of Plaintiffs’ APA claim asserts that TTB exceeded its statutory authority by relying on the FDA’s analysis in evaluating Bellion’s petition. Bellion’s proposed extra-record evidence, which goes to whether their asserted health benefits are substantiated by credible science, has no bearing on the merits of their APA claim.

B. Constitutional Claims

The propriety of extra-record evidence for Bellion’s three constitutional claims, conversely, warrants further scrutiny. Plaintiffs mount their attack from two fronts. First, they contend that this case falls into one of the accepted circumstances in which a party is permitted to supplement an administrative record on judicial review. Second, Bellion says that the Court need not actually rely on these exceptions at all. Rather, they assert, the fact that they bring constitutional claims frees them of the limitations of APA review. Neither argument persuades.

1. Accepted Exceptions

Taking the accepted exceptions first, Plaintiffs have not shown that their case falls into one of the four “highly exceptional[] circumstances” in which a party may supplement an administrative record. See Cape Hatteras Access Preservation Alliance, 667 F. Supp. 2d at 114–15. The Court can knock out two of the four exceptions right off the bat: Bellion makes no assertion that the agency “acted in bad faith” or otherwise “engaged in improper behavior.”

Styrene Info. & Research Ctr., 851 F. Supp. 2d at 63. Two remain: situations in which an agency “failed to examine all relevant factors” or “failed to explain adequately its ground for decision.”

Id.

Bellion’s arguments on these grounds land wide of the mark. Although they repeatedly maintain that TTB “failed to examine all relevant factors,” the grievances that back up this assertion have little to do with an agency’s neglect of a factor that it was obligated to address. They say, for instance, that “TTB based its decision on factors that could not have been foreseen by Bellion,” Pl. Motion at 8 — *i.e.*, by consulting with the FDA — and that the “abdication of TTB’s statutory obligations” — again, by consulting with the FDA — “involved TTB’s failure to consider all relevant factors.” Pl. Reply at 3. Tacking, Bellion also asserts that “[b]y refusing to provide Bellion with an opportunity to present [its] evidence below before it issued a Decision[,] . . . TTB failed to examine all relevant factors.” Id. at 12-13.

These are simply not the circumstances contemplated by the exception. Nowhere does Bellion point the Court to a specific factor that TTB was required, but failed, to examine and that the Court must also consider on judicial review. This is what the exception demands. See, e.g., United Student Aid Funds, 237 F. Supp. 3d at 5 (permitting extra-record evidence when administrative agency failed to articulate whether its policy differed from industry practice or otherwise constituted a change in position); Cape Hatteras Access Preservation Alliance, 667 F. Supp. 2d at 116 (denying a motion because plaintiffs had “not identified any particular factors [the agency] failed to consider” nor “what factors [the agency] needed to consider”). If an agency never considered a factor that the reviewing court must evaluate, “reviewing agency action would be unnecessarily difficult.” Cape Hatteras Access Preservation Alliance, 667 F. Supp. 2d at 114.

That is not the case here. Bellion’s primary arguments all trace back to their unhappiness with TTB’s decision to involve the FDA. This decision does not establish, however, that TTB failed to consider a relevant factor. Perhaps, as Plaintiffs contend, they were not afforded a sufficient opportunity to counter the agencies’ findings before TTB, or perhaps, as the Government argues, these processes were adequate. That dispute is for another day. What matters here is that, regardless of its merit, TTB’s decision does not deprive the Court of a sufficient administrative record to evaluate the agency’s finding on a relevant factor. In fact, on the key question to which Bellion’s proposed extra-record evidence is relevant — whether their health claims are true (or, at least, not false) — the administrative record already contains a heap of studies and articles submitted by Bellion to TTB (112, to be precise) along with additional expert reports. See Pl. Motion at 3.

Lurking behind this deficiency in Plaintiffs’ argument is a larger one. It is only in Bellion’s APA count (Count III) that they specifically target TTB’s interaction with the FDA. As already detailed, however, Plaintiffs concede that the Court need not admit extra-record evidence to evaluate this part of their suit. To succeed in admitting extra-record evidence on their constitutional claims, the “relevant factor” must be one relevant to the constitutional analysis. Plaintiff has articulated no connection — and the Court discerns no link — between TTB’s purported “statutory abdication” and this analysis.

Bellion does say, however, that “[b]y refusing to provide Bellion with an opportunity to present [its] evidence below before it issued a Decision[,] . . . TTB failed to examine all relevant factors.” Pl. Reply at 12–13. To the degree this statement is intended to refer to Bellion’s contention in its Motion that TTB’s process is constitutionally inadequate because it did not give Bellion an opportunity to respond, it does not help them. Bellion’s desire to critique the

agencies' analysis implies not that the agency failed to consider a factor, but that Bellion disagrees with its conclusion as to those factors.

The nature of the evidence Bellion seeks to add confirms that its actual beef is with the substance of the agency's decision. Such a position does not permit Bellion to supplement the record. As the Court of Appeals has stated, "[T]he familiar rule that judicial review of agency action is normally to be confined to the administrative record . . . exerts its maximum force when the substantive soundness of the agency's decision is under scrutiny." Esch v. Yeutter, 876 F.2d 976, 991 (D.C. Cir. 1989). TTB already considered the two studies Bellion seeks to add; only the fact of peer review — which occurred after TTB's decision — is new. Because the agency already considered and addressed these studies, see Def. Opp. at 4, there can be no real argument that peer review supplements a record "silent" on an "unresolved factual issue." United Student Aid Funds, 237 F. Supp. 3d at 5. Bellion also seeks to submit a declaration verifying that Bellion Vodka contains the compounds studied in its submitted articles. It contends that the record is silent on this point, thus permitting supplementation. See Pl. Reply at 12. But the record is "silent" not because TTB "failed to consider a relevant factor" — in fact, it expressly addressed this logical link — but because Bellion never submitted evidence to the agency. Plaintiffs do not get a do-over in this Court. See Bradley v. Weinberger, 483 F.2d 410, 415 (1st Cir. 1973) (characterizing judicial review of agency action as a "re-view, a second look at the same material, not a re-doing").

Even more probative, two of the declarations' stated purpose is to attack the substance of TTB's decision and FDA's memorandum and demonstrate why the "DNA Claims are substantiated by credible evidence." Pl. Motion at 13. This charge, quite clearly, attempts to strike at the substantive heart of FDA's decision. Where Plaintiffs' complaint is with the

substance of the decision rather than the agency's failure to consider any relevant factor, they are confined to the administrative record.

For similar reasons, Bellion's contention that the agency failed to adequately explain its reasoning is unavailing. Plaintiffs contend that the agency's decision is "void of any foundational explanation in science for its conclusion that the two DNA claims were invalid." Pl. Motion at 9. TTB, however, articulated its reason for denying Bellion's claim in a 47-page letter. See Petition Response Letter. Bellion may very well disagree with its conclusion. But "[t]his is not a case where the agency failed 'to explain administrative action [so] as to frustrate effective judicial review.'" IMS, 129 F.3d at 624 (quoting Camp, 411 U.S. at 142–43). This Court has previously pointed out that "[d]isagreement with an agency's analysis is not enough to warrant the consideration of extra-record evidence." Standing Rock Sioux Tribe v. U.S. Army Corps of Engineers, 255 F. Supp. 3d 101, 125 (D.D.C. 2017).

Finally, Bellion sprinkles throughout its briefs additional arguments untethered to any of the specified exceptions. Most prominently, they point out that supplementing the record may be appropriate where "the procedural validity of the agency's action remains in serious question." CTS Corp. v. EPA, 759 F.3d 52, 64 (D.C. Cir. 2014) (quoting Hill Dermaceuticals, 709 F.3d at 47). Here, Plaintiffs say, they have brought a challenge to the agency's procedures, thus entitling them to a broader record. See Pl. Reply at 10. Bellion misunderstands the law. A plaintiff is not entitled to supplement the record merely because she challenges an agency's procedures. See Esch, 876 F.2d at 991 (noting that it is only "sometimes" appropriate to admit extra-record evidence when procedural validity of an agency action is challenged). Such a categorical exception would threaten to swallow the rule. Rather, it is only where there are "gross procedural deficiencies" that render the "administrative record . . . so deficient as to preclude

judicial review” that a plaintiff may add more than the agency had before it. See CTS Corp., 759 F.3d at 64 (quoting Hill Dermaceuticals, 709 F.3d at 47); see also Esch, 876 F.2d at 992 (permitting supplementation where agency “failed woefully in complying with the hearing requirement” such that “[n]one of the proceedings that did occur was conducted in a manner conducive to obtaining the relevant facts”); United Student Aid Funds, 237 F. Supp. 3d at 6 (finding that lack of any evidence on key issue was a qualifying “gross procedural deficiency”). Here, on the other hand, for the reasons already mentioned, the administrative record is sufficiently developed on the challenged points. The Court, therefore, concludes that none of the accepted exceptions applies.

2. Constitutional Argument

Perhaps anticipating this conclusion, Plaintiffs alternatively offer a different approach. They eschew any reliance on the exceptions addressed above and instead argue that because their claim originates under the Constitution, the strictures of the APA do not apply. As a quick reminder, Plaintiffs assert three constitutional causes of action. Bellion’s first constitutional claim (Count I) arises under the First Amendment and challenges the agency’s finding that their health claims are misleading and insufficiently substantiated. Counts II (also under the First Amendment) and IV (under the Fifth Amendment), conversely, take issue with the procedures employed by TTB. Because the proposed extra-record evidence either criticizes the agencies’ analysis or adds purported substantiation for Bellion’s health claims, it is most clearly relevant to Count I. It is with that count, therefore, that the Court begins.

The caselaw on a plaintiff’s ability to supplement an administrative record to support a constitutional cause of action is sparse and in some tension. See, e.g., Chiayu Chang v. U.S. Citizenship & Immigration Servs., 254 F. Supp. 3d 160, 161 (D.D.C. 2017) (noting “some

disagreement among district courts” on this issue). Lacking explicit support in caselaw, Plaintiffs’ primary argument leans on the Court’s independent role in reviewing constitutional claims. See Pl. Motion at 9–10; Pl. Reply at 4–9. The Court agrees that this is the place to start.

Plaintiffs set forth the principle that constitutional claims are typically reviewed *de novo*. See Pl. Motion at 9. As a general matter, they are correct. See Nat’l Oilseed Processors Ass’n v. Occupational Safety & Health Admin., 769 F.3d 1173, 1179 (D.C. Cir. 2014). But *de novo* review does not mean the same thing in all contexts. The D.C. Circuit recently held that, “even in the First Amendment context,” a court must review certain agency “factual finding[s] . . . under the ordinary (and deferential) substantial-evidence standard.” POM Wonderful, LLC v. FTC, 777 F.3d 478, 499 (D.C. Cir. 2015). District courts in this circuit, addressing claims substantially similar to those at issue here, reached the same conclusion prior to the D.C. Circuit’s affirmation in POM Wonderful. See, e.g., Alliance for Nat. Health U.S. v. Sebelius, 786 F. Supp. 2d 1, 12 n.11 (D.D.C. 2011) (“The Court reviews an agency’s decisions on constitutional issues *de novo*, but defers to an agency’s interpretation of scientific information unless it is irrational or arbitrary and capricious.”). When the time comes, this Court will thus review *de novo* any question of constitutional law but must apply the substantial-evidence test and accord some deference to the agency’s scientific and fact-bound determinations.

Under this test (or any test, for that matter), evaluating an agency’s decision rooted in complex scientific data is no easy lift. Reacting to this complexity, circuit precedent dictates that a reviewing court’s task is to critically analyze the agency’s logic and explanation rather than engage in a comparative evaluation of conflicting scientific evidence. See Whitaker v. Thompson, 248 F. Supp. 2d 1, 11 (D.D.C. 2002). Its object is to ensure that the agency “explicated the bases of its decision, and adduced substantial evidence in the record to support its

determinations.” Nat’l Oilseed Processors Ass’n, 769 F.3d at 1178. More specifically, this process includes requiring the agency “to explain the logic and the policies underlying any . . . choice,” “state candidly any assumptions on which it relies,” and “present its reasons for rejecting significant contrary evidence and argument.” Id. (quoting United Steelworkers of Am., AFL–CIO–CLC v. Marshall, 647 F.2d 1189, 1207 (D.C. Cir. 1980)).

This task would be markedly harder with a supplemented record. There would be little meaningful way to review the logic of an agency’s attempt to sort through scientific evidence and the bases of its decision if the record before the court differed from that before the agency. This is especially so for a scientific claim in a commercial-speech context. In this case, a court may be called on to review an agency’s determination about the credibility of scientific evidence in support of a health claim and whether that evidence is “qualitatively weaker than the evidence against the claim.” Whitaker, 248 F. Supp. 2d at 10 (quoting Pearson v. Shalala, 164 F.3d 650, 659 n.10 (D.C. Cir. 1999)). Plaintiffs’ approach would have the Court make these credibility determinations in the first instance. This is not the Court’s role nor is it consistent with the substantial-evidence standard. See id. at 11 (“[I]t is generally ‘not for the judicial branch to undertake comparative evaluations of conflicting scientific evidence.’”) (quoting NRDC v. EPA, 824 F.2d 1211, 1216 (D.C. Cir. 1987)).

Said otherwise, the gravamen of Bellion’s constitutional complaint in Count I faults a decision made by an administrative agency — namely, its conclusion that Bellion’s health claims are misleading. The Court’s evaluation of the agency’s decision is not aided by considering evidence to which the agency was not privy. The nature of Bellion’s assertion and the method in which the Court is obligated to review the agency’s scientific conclusions in this case, buttressed by practical considerations, thus militate in favor of treating Bellion’s first First Amendment

claim (Count I) in the same manner as a similar challenge brought under the APA — *i.e.*, confined to the administrative record.

For these and similar reasons, district courts have been hesitant to permit a plaintiff asserting a constitutional challenge to agency action to avoid the APA's bar on extra-record evidence. For example, one court bound a plaintiff's First Amendment claim to the APA's procedural provisions because the case was "an appeal of an agency action in every respect" and permitting a broader record on judicial review for a constitutional claim would "incentivize every unsuccessful party to agency action to allege bad faith, retaliatory animus, and constitutional violations to trade in the APA's restrictive procedures for the more even-handed ones of the Federal Rules of Civil Procedure." Jarita Mesa Livestock Grazing Ass'n v. U.S. Forest Serv., 58 F. Supp. 3d 1191, 1237–38 (D.N.M. 2014). Other courts have followed similar reasoning. See Chiayu Chang, 254 F. Supp. 3d at 161–62; Harvard Pilgrim Health Care of New England v. Thompson, 318 F. Supp. 2d 1, 10 (D.R.I. 2004) ("The APA's restriction of judicial review to the administrative record would be meaningless if any party seeking review based on statutory or constitutional deficiencies was entitled to broad-ranging discovery."); Ketcham v. U.S. Nat'l Park Serv., No. 16-17, 2016 WL 4268346, at *1–2 (D. Wyo. Mar. 29, 2016) (holding that court was "obligated" to analyze a suit asserting constitutional claims under "the procedures set forth under the APA" because "distinguish[ing] between a 'stand-alone constitutional challenge' and an 'APA challenge,' . . . would run afoul of Congress's intent"); Alabama-Tombigbee Rivers Coal. v. Norton, 2002 WL 227032, at *5–6 (N.D. Ala. Jan. 29, 2002) (denying plaintiff's request for discovery for its constitutional claim because "when there is a contemporaneous explanation of the agency decision, the validity of that action must stand or fall on the propriety of that finding" and whether it is "sustainable on the administrative record

made”) (quoting Vermont Yankee Nuclear Power Corp. v. NRDC, Inc., 435 U.S. 519, 549 (1978)).

There appears to be a common thread running through these cases: when a constitutional challenge to agency action requires evaluating the substance of an agency’s decision made on an administrative record, that challenge must be judged on the record before the agency. In fact, the one case cited by Bellion in which a court permitted extra-record evidence for a constitutional claim accords with this principle. See Rydeen v. Quigg, 748 F. Supp. 900, 906 (D.D.C. 1990). In Rydeen, the constitutional challenge – under the Due Process Clause – did not require the court to review the substance of an agency’s decision. Rather, it challenged the procedures by which the agency reached its conclusion. Id.

So here is the bottom line: Given the dearth of caselaw on point in this circuit, the Court declines to adopt any bright line or categorical rule. It finds that in this particular case, Bellion is not entitled to supplement the administrative record for any constitutional claim that requires the Court to analyze the substance of an agency’s decision that is, in turn, based on an evaluation of that record. This conclusion disposes of Plaintiffs’ Motion with respect to its First Amendment claim challenging the agency’s conclusion that Bellion’s health claims are misleading or inadequately substantiated (Count I).

In Counts II and IV, however, Plaintiffs challenge the agency’s procedures rather than the substance of its decision. Bellion contends in Count II that TTB’s procedures amount to an unconstitutional prior restraint in violation of the protections afforded by the First Amendment. Count IV raises a challenge under the Fifth Amendment — namely, that TTB regulations are unconstitutionally vague. Because these claims do not require the Court to evaluate the substance of the existing administrative record, the prior analysis does not necessarily apply.

Rather, the question here is whether Plaintiffs' proposed evidence is relevant to their allegations. It would be an exercise in futility to permit extra-record evidence that has no bearing on Bellion's claims.

The Court would forgive a careful reader for being confused by Bellion's assertion that its evidence is relevant to its procedural claims. Plaintiffs conceded, as earlier mentioned, that "[n]one of Bellion's proposed extra-record evidence is relevant to Bellion's APA claim," which, like the constitutional claims, attacks the procedures employed by TTB. See Pl. Reply at 5. Similarly, nowhere in Bellion's Motion do they connect their extra-record evidence to their procedural arguments. On the other hand, they explicitly assert that the declarations and peer-reviewed articles attack the substance — rather than procedure — of FDA's conclusion. They say, for example, that the Blumberg declaration is "probative of whether [the] DNA Claims are substantiated by credible evidence" and "challenge[s] the scientific deficiencies that were overlooked by the TTB in its Decision." Pl. Motion at 13–14.

After the Government pointed out this logical disconnect, Bellion changed tack in their Reply. There, Plaintiffs contend that "each of the items Bellion seeks to add to the record are relevant to the issue of whether TTB's procedural process was valid." Pl. Reply at 12. Bellion says that the Chigurupati declaration — which "respond[s] to a specific critique of TTB" — "proves that if TTB provided Bellion with sufficient notice of the standards upon which it would adjudge Bellion's substantiation, Bellion could have quickly included the . . . declaration in the record below." Id. Similarly, Bellion contends that the two expert declarations "support Bellion's argument that TTB's procedure is invalid" because, had TTB "provided Bellion with a trial-like process, Bellion would have offered" the testimony in rebuttal. Id. at 14.

As an initial matter, the Court is skeptical that these substantive declarations can prove that Bellion was afforded a constitutionally inadequate process in the manner asserted in Counts II and IV. Such a ruling, however, might dance too close to the merits of Plaintiffs' claim, which will be the subject of future merits briefing. The Court thus grants for now the premise that Bellion's inability to respond to the agency's conclusion could be relevant to Counts II and IV. The question then becomes whether Plaintiffs need to supplement the record in order to demonstrate this connection. They do not. On the existing record, they are free to assert in future briefing, for instance, that TTB never offered them a chance to respond. Should the Government argue that such response would not change the outcome, Bellion is similarly free to outline the contours of the evidence they would have presented. For this, they also need not supplement the record. Plaintiffs thus do not explain, nor does the Court discern any reason, why admitting the declarations now would help them in making their case for Counts II and IV. Said otherwise, admitting the extra-record evidence does not advance the ball for Plaintiffs beyond their current position. On the briefing before it, the Court thus concludes that Bellion cannot bootstrap in evidence attacking the substance of the agency's decision merely by asserting that they would have submitted this evidence had the procedures been as they desired.

This is not to say, however, that Bellion is without remedy. If Plaintiffs believe that the administrative record is too incomplete to give them a fair shake, their request should be directed to the agency to consider the evidence in the first instance, not this Court. See CTS Corp., 759 F.3d at 65 (noting similarly). The Government posits, and this Court has no reason to doubt, that Bellion could submit a motion for reconsideration of the agency's decision or file a new petition in which they incorporate their additional evidence. See Def. Opp. at 15. Similarly, Bellion

remains free to criticize the merits of TTB's decision. It must do so, however, without resort to extra-record evidence.

IV. Conclusion

For these reasons, the Court will deny Plaintiffs' Motion to File Extra-Record Evidence.

A separate Order so stating will issue this day.

/s/ James E. Boasberg
JAMES E. BOASBERG
United States District Judge

Date: September 27, 2018